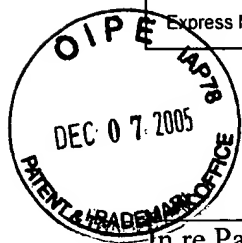




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Docket No.: 03042/000G956-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
James D. Marks

Application No.: 09/556,945

Confirmation No.: 6556

Filed: April 21, 2000

Art Unit: 3626

For: SYSTEM AND METHOD FOR
RECRUITMENT OF CANDIDATES FOR
CLINICAL TRIALS WHILE MAINTAINING
SECURITY

Examiner: R. W. Morgan

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

REMARKS

A non-final Office Action was mailed on October 21, 2005 in regard to the above-referenced patent application. As this Office Action is the sixth Office Action generated during the prosecution of this application, Applicant properly elects to file a Notice of Appeal under 35 U.S.C. § 134 to appeal the current rejection of claims 151 - 203. Concurrently with this Notice of Appeal, and in advance of filing an Appeal Brief, Applicant files this Request for a Pre-Appeal Brief Review of the rejection of claims 151 - 203 under the present Pre-Appeal Brief Conference Pilot Program. In view of the following remarks, Applicant respectfully submits that claims 151 - 203 stand in condition for allowance, and requests that a Notice of Allowance be issued in this case.

PROSECUTION HISTORY

The present application (U.S. Patent Application Serial No. 09/556,945) was filed on April 21, 2000, including 54 claims. A Preliminary Amendment adding claims 55 - 62 was mailed on November 17, 2000.

A first Office Action mailed on February 3, 2003 rejected each of claims 1 - 62 as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al. in view of U.S. Patent No. 6,171,112 to Clark et al., in view of Clark and Official Notice, or in view of Clark and U.S. Patent No. 6,272,470 to Teshima. Applicant mailed a Response to this Office Action on July 21, 2003, amending claims 1, 3, 4, 15, 23, 32 - 34, 46, 51, and 53, and adding new claims 63 - 148. A final Office Action was mailed on October 7, 2003, withdrawing claims 73 - 148 from consideration by restriction and rejecting claims 1 - 72 on the basis of the same references. Applicant held a telephonic interview with the Examiner and his supervisor ("the Examiners") on December 23, 2003, and mailed a Response to the final Office Action on January 7, 2004, canceling claims 105 - 125 and amending claims 1, 2, 15, 19 - 21, 25, 26, 31, 34 - 41, 44 - 46, 48 - 50, 53 - 57, 59, 61 - 64, 67, 69, 70, 73, 74, 77, 79, 80, 82 - 90, 92, 94 - 98, 100, 102 - 104, 131, 132, 134 - 136, 138, 139, 141, 143, 144, and 147. In response to an Advisory Action of February 24, 2004, Applicant mailed a Request for Continued Examination (RCE) on March 5, 2004, entering the Response of January 7, 2004.

On March 30, 2004, in the interests of furthering prosecution, Applicant mailed a Preliminary Amendment canceling claims 1 - 72, amending claims 73 - 75, 77, 79, 80, 82 - 90, 92, 94 - 98, 100, 102 - 104, 131, 132, 134 - 136, 138, 141, 143, 144, and 147, and adding new claim 149. A non-final Office Action was mailed on May 19, 2004, rejecting claims 73 - 104 and 126 - 149 based on some of the earlier-applied references and "drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patient on the Internet" by PR Newswire. Applicant mailed a Response on August 19, 2004, enclosing declarations under 37 C.F.R. § 1.131 to establish a date of invention preceding the date of the PR Newswire reference (June 28, 1999). A non-final Office Action was mailed on December 8, 2004, rejecting claims 73 - 104 and 126 - 149 based on the some of the earlier-applied references and "Web links cancer patients to drug trials" by Machlis.

Applicant held another telephonic interview with the Examiners on February 9, 2005, and based on the their recommendations for amendment and a belief that patentable features of the

invention had been agreed upon, mailed a Response on March 8, 2005, amending claims 73, 76, 77, 79, 131, 134, 138, 143 and 147, and adding new claims 150 - 156. A final Office Action was mailed on June 7, 2005, rejecting claims 73 - 104 and 126 - 156 based on some of the earlier-applied references. Applicant held additional telephonic interviews with the Examiner on August 4, 2005 and August 17, 2005. Once again believing that an agreement as to patentable features had been reached, Applicant mailed an RCE and Preliminary Amendment on September 13, 2005, canceling claims 73 - 104 and 126 - 150 and adding new claims 157 - 203. A non-final Office Action was mailed on October 21, 2005, rejecting claims 151 - 203 based on the earlier-applied references and a second PR Newswire reference ("Go Network™ and drkoop.com Strike Exclusive \$57 Million Cross-Network Partnership"). In Applicant's estimation, notwithstanding the apparent agreement earlier as to patentability, the examiner nonetheless continued to set about to find still other references which would support new rejections, as if directed not to allow any of the claims presented in this application. Accordingly, this Request for Pre-Appeal Brief Review is being filed in response to the Office Action of October 21.

THE CLAIMED INVENTION

In the present application, Applicant discloses and claims a system and method for the on-line recruitment of candidates for a plurality of clinical trials. With reference for example to Applicant's current claim 152, the disclosed method includes the steps of:

- providing an enrollment interface generated by a server over a computer network for access by a plurality of remote computer terminals, the enrollment interface including an agreement volunteering for consideration as a potential candidate for the clinical trials, whereby a plurality of remote individuals can provide electronic consent to the agreement via the remote computer terminals;

- receiving the electronic consent from at least two of the remote individuals on the enrollment interface, each of the two remote individuals being a potential candidate; and
- adding at least one piece of medical information for each of the two remote individuals to a database of individuals available for enrollment in the clinical trials.

Once stored in the database, information about the potential candidates is provided to representatives of the clinical trials, who further screen the potential candidates and contact candidates of interest for follow-up. As described at pages 1 and 2 of Applicant's specification, the disclosed invention improves over the prior art by enabling individuals who are interested in

HOW THE CLAIMED INVENTION IS DISTINGUISHED OVER THE REFERENCES

In the Office Action of October 7, the Examiner suggested that this deficiency may be overcome with the addition of U.S. Patent No. 6,171,112 to Clark et al. Clark discloses a system for medical staff to educate patients already identified for treatment about various treatment options as means for electronically obtaining the patients' informed consent before beginning treatment. As argued at page 29 of Applicant's Response of July 18, this system is quite distinct from Applicant's claimed invention, in which consent and medical and/or other personal information is provided directly by a candidate who thereby self-identifies in order to be considered as a participant in one or more clinical trials. Applicant argued that even if Clark were combined with Colon, the combination would still fail to teach Applicant's claimed invention, as Colon teaches away from providing a trial candidate or patient with direct access to the disclosed system.

In the Office Action of December 8, 2004, the Examiner substituted “Web links cancer patients to drug trials” by Machlis for the first PR Newswire reference. Machlis discloses a database including information about cancer patients which may be used to prescreen candidates for new drug trials. The Machlis system as described is only open to subscribing doctors, who provide only data currently recorded in patient files. As argued at page 14 of Applicant’s Response of March 8,

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